



October 5, 2005

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-18

Animal and Plant
Health Inspection
Service

Subject: Canine Influenza Virus Vaccine and Related Diagnostic Test Kits

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS
State Veterinarians

Center for Veterinary
Biologics

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Veterinary Services Management Team
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I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is accepting veterinary biologics product license and permit applications for Canine Influenza Virus Vaccine and related diagnostic test kits.

II. BACKGROUND

Recent outbreaks of respiratory disease in canines in the United States have been linked to canine influenza virus. Originally observed in greyhound dogs, the virus lately has spread to other canine populations. Serological and molecular evidence suggests that the causative agent is closely related to equine influenza A (H3N8) virus. Confirmed cases have been reported in several states.

III. ACTION

The CVB will consider license and permit applications for Canine Influenza Virus Vaccine and related diagnostic test kits. Interested parties should refer to Title 9, Code of Federal Regulations, Subchapter E; Veterinary Services (VS) Memorandum 800.50, Basic License Requirements for Applicants; VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale; and VS Memorandum 800.73, General Requirements for Immunodiagnostic Test Kits for the Detection of Antibody or Antigen, for guidance. This information is available on the CVB website:
www.aphis.usda.gov/vs/cvb/regsandguidance.htm

Applications and supporting materials should be submitted to the CVB-Policy, Evaluation, and Licensing for review.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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